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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,433	09/22/2003	Steven A. Daniel	37167-8042.US01	2354
22918	7590	09/30/2005	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/668,433	Applicant(s) DANIEL ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21 is/are rejected.
- 7) ☒ Claim(s) 20, 22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/12/03</u> | 6) <input type="checkbox"/> Other: _____ |

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Specification

The disclosure is objected to because of the following informalities: the first sentence of the specification should be amended to provide the most current status (i.e. US Patent Number) for the parent application to which priority is claimed.

Appropriate correction is required.

Claim Objections

Claims 1, 5, 10, 15 and 16 are objected to because of the following informalities: claims 1, 5, 10, 15 and 16 all lack proper antecedent basis for "said tip" or "said distal tip". It is assumed applicant intended to recite in the independent claims "an instrument having a tip". Applicant should consider using consistent terminology (e.g. "tip" or "distal tip") throughout the claims when changes are made.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Cosman (6,241,725).

Cosman provides a system for treating tumors comprising an instrument (3, 303) having a distal end structure adapted to be inserted into a bone tumor. A connecting structure (7,207) connects the distal end structure to an RF activating device (224). The instrument further includes a probe (2, 202, 302) through which an electrode (i.e. instrument) is movable from a retracted position to a deployed position.

Claims 1-4, 6, 8-14, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Cosman et al (6,478,793).

Cosman et al disclose a system for treating tumors in bone tissue comprising an instrument having a distal end structure (7) that is inserted into bone tissue. The instrument is connected to a source of RF energy (17) for ablating the tumor. The instrument further includes a probe (142) with a distal end and at least one electrode movable from a retracted position to an extended position within the bone (see Figures 3 and 5). Cosman et al further provide for the insertion of multiple electrodes (Figure 5) including electrodes that deploy with curvature (404, 432 in Figure 5). With regard to claim 8, the examiner maintains that the probe (i.e. probe 142 of Figure 3) includes a central lumen through which a fluid may be introduced when the electrode is not present. The method of using the device is fully disclosed and depicted in the Cosman et al patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al (793) in view of the teaching of LeVeen et al (5,827,276).

Cosman et al disclose RF electrode devices that are deployable into bone tissue for treating tumors therein. Cosman et al further disclose deploying electrodes having a preformed (i.e. curved) shape, as well as the use of plural electrodes (Figure 5). However, Cosman et al fail to specifically disclose deploying a plurality of electrodes from a single probe member.

LeVeen et al discloses another deployable electrode device substantially identical (structurally) to the Cosman et al device. In particular, LeVeen et al teach that it is known to deploy multiple electrodes in an array from a single probe device to create a three dimensional lesion area for treating tumor tissue.

To have provided the Cosman et al device with multiple electrodes deployable from a single introducer to create a larger ablation site within tumor tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of LeVeen et al.

Claims 3-8, 13-19 and 21/19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman et al (793) in view of the teaching of Gough et al (5,672,173).

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Again, Cosman et al fail to disclose deploying multiple electrodes from a single probe device. Further, while Cosman et al disclose circulating a fluid through the electrode member to cool the electrode, there is no specific teaching of providing a means to deliver fluid to tumor tissue.

Gough et al disclose another deployable electrode device substantially identical to the Cosman et al and LeVeen et al systems. It includes a plurality of RF electrodes deployable from a single introducer. The electrodes are deployed to create a desired tissue ablation volume within a tumor, and the electrodes are needles with lumens for injecting a fluid to tumor tissue (col. 7, lines 55-65).

To have provided the Cosman et al device with a plurality of electrodes deployable from the introducer to create a desired ablation volume in tumor tissue would have been an obvious modification for one of ordinary skill in the art. To have further provided the electrodes with a distal open for injecting fluid into the tumor as an additional treatment modality would have been an obvious consideration for one of ordinary skill in the art in view of the Gough et al teaching.

Allowable Subject Matter

Claims 20, 21/20, 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

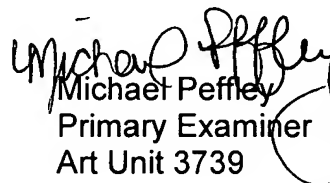
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Sharps et al (6,602,248) and Underwood et al (6,264,651) disclose other RF electrosurgical devices for treating tissue within bone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
September 29, 2005